

Notice of Allowability

Application No.

09/972,794

Examiner

Dave T. Nguyen

Applicant(s)

AMALFITANO ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to March 11, 2004.
2. ☒ The allowed claim(s) is/are 1, 4-5, 13, 15, 26-41, 59-70, 75, 80, 82-86, 94-98, 105-109, 111-116, 133, 146, 148 and 207-222.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date 13.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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Claims 44, 50, 52, 54, 55, and 81 have been canceled, claims 35, 80, 82, and 107 have been amended by the amendment filed March 15, 2004.

Claims 1-5, 13, 15, 16, 25-41, 59-70, 75, 80, 82-86, 94-98, 105-109, 111-116, 132, 133, 146-148 and 207-222

are pending prior to the following examiner's amendment.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a personal interview with Attorney Karen Magri on April 2, 2004.

Applicant's response and applicant's amendment to claims 80 and 82 have been considered and is found persuasive for the withdrawal of the prior art rejections. The following examiner's amendment is to update the status of the parent '749 application, and to correct informal matters, antecedent basis recitations, and to clarify that the claimed propagation defective adenovirus vector comprising at least a heterologous nucleic acid sequence for expression is capable of being propagated in a complementing cell line without a helper, and does not encompass a gutted adenovirus vector.

In the specification:

In the specification, first paragraph (referred and entered by the preliminary amendment dated May 10, 2001), please changed the "(now allowed)" to

-- , now US Pat No. 6,328,958 --.

In the specification, page 6, line 18, "Figure 1 shows" has been changed to

-- Figures 1A-1C show --.

In the specification, page 6, line 19, the "Panel A" has been changed to

-- Figure 1A --.

In the specification, page 6, line 19, the "Panel B" has been changed to

-- Figure 1B --.

In the specification, page 6, line 20, the "Panel C" has been changed to

-- Figure 1C --.

In the specification, page 35, line 31, "Transf r" has been changed to

-- **Transfer** --.

In the specification, page 46, line 25, "**Figure 1, Pannel A**" has been changed to

-- **Figure 1A** --.

In the specification, page 47, line 1, "**Figure 1, Pannel B**" has been changed to

-- **Figure 1B** --.

In the specification, page 48, line 1, "**Figure 1, Pannel C**" has been changed to

-- **Figure 1C** --.

In the specification, page 48, line 5, "**Figure 1, Pannel C**" has been changed to

-- **Figure 1C** --.

The following claims have been amended as indicated below:

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1. (Currently Amended) A propagation-defective adenovirus vector comprising a recombinant adenovirus genome comprising a heterologous nucleotide sequence, wherein the genome [that] lacks a coding sequence for a functional adenovirus 100K protein, and wherein said adenovirus vector can be propagated in a transcomplementing cell in the absence of a helper.

Claim 2 has been canceled.

In claims 4-5, 13, 27-30, 32-34, 36-41, 60-65, 67-68, 70, line 1, insert the
-- vector -- between "adenovirus" and "of".

15. (Currently Amended) The adenovirus vector of claim 4, wherein said adenovirus vector is disclosed herein as [E1⁻, 100K⁻]Ad.

Claims 3, 16, and 25 have been canceled.

26. (Currently Amended) The adenovirus vector of claim 1 [25], wherein said heterologous nucleotide sequence[(s)] is operatively associated with expression control sequences.

31. (Currently Amended) The adenovirus vector of claim 1 [25], wherein said heterologous nucleotide sequence[(s)] encodes a protein or peptide.

35. (Currently Amended) The adenovirus vector of claim 1 [25], wherein said heterologous nucleotide sequence[(s)] encodes an antisense nucleotide sequence or non-translated DNA.

59. (Currently Amended) A propagation-defective adenovirus vector comprising a recombinant adenovirus genome comprising a heterologous nucleotide sequence encoding a lysosomal acid α -glucosidase, wherein the genome [that] lacks a coding sequence for a functional adenovirus 100K protein, and wherein said adenovirus vector can be propagated in a transcomplementing cell in the absence of a helper [and comprises a heterologous nucleotide sequence encoding a lysosomal acid α -glucosidase].

66. (Currently Amended) The adenovirus vector of claim 59, wherein said lysosomal acid α -glucosidase [protein or peptide] is human lysosomal acid α -glucosidase.

69. (Currently Amended) An isolated [A] mammalian cell comprising the adenovirus vector of Claim 1.

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75. (Currently Amended) An isolated [A] mammalian cell comprising the adenovirus vector of Claim 59.

In claim 80, line 5, insert -- adenovirus -- between "functional" and "100K".

In claim 86, line 3, insert -- adenovirus -- between "functional" and "100K".

94. (Currently Amended) An isolated DNA comprising a recombinant adenovirus genome comprising a heterologous nucleotide sequence, wherein the genome [that] lacks a coding sequence for a functional adenovirus 100K protein, and wherein said recombinant adenovirus genome can be propagated in a transcomplementing cell in the absence of a helper.

105. (Currently Amended) A method of producing a propagation-defective adenovirus vector, comprising:

introducing the [a] propagation-defective adenovirus vector of claim 1 into a mammalian cell[, wherein the introduced propagation-defective adenovirus comprises a recombinant adenovirus genome that lacks a coding sequence for a functional 100K protein];

wherein the mammalian cell expresses a functional adenovirus 100K protein and transcomplements the function(s) lacking from the adenovirus genome; and

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collecting the propagation-defective adenovirus vector produced by said mammalian cell.

In claim 106, line 1, insert -- vector -- between "adenovirus" and "has".

In claim 112, line 1, insert -- vector -- between "adenovirus" and "is".

In claim 113, line 2, insert -- adenovirus -- between "functional" and "100K".

In claim 115, line 2, insert -- adenovirus -- between "functional" and "100K".

In claim 116, line 2, insert -- functional adenovirus -- between "the" and "100K".

Claim 132 has been canceled.

146. (Currently Amended) A method of producing a propagation-defective adenovirus vector, comprising:

introducing a bacterial plasmid comprising a recombinant adenovirus genome into a bacterial cell, wherein said adenovirus genome comprises a heterologous nucleotide sequence and lacks a coding sequence for a functional adenovirus 100K protein, and wherein said adenovirus genome can be propagated in a transcomplementing cell in the absence of a helper;

amplifying the bacterial plasmid in the bacterial cell;

recovering the amplified bacterial plasmid from the bacterial cell;

linearizing the recovered bacterial plasmid;

introducing the linearized plasmid into a mammalian cell that
transcomplements the deleted functions in the adenovirus genome; and
collecting the propagation-defective adenovirus vector.

Claim 147 has been canceled.

148. (Currently Amended) The method of Claim 146 [147], wherein the
heterologous nucleotide sequence encodes a lysosomal acid α -glucosidase.

In claim 207, line 3, insert -- adenovirus -- between "functional" and "100K".

In claim 210, line 3, insert -- adenovirus -- between "functional" and "IVa2".

In claim 211, line 3, insert -- adenovirus -- between "functional" and
"polymerase".

In claim 212, line 3, insert -- adenovirus -- between "functional" and "preterminal".

In claim 213, line 2, insert -- adenovirus -- between "functional" and "100K".

In claim 215, line 2, insert -- adenovirus -- between "functional" and "100K".

In claim 216, line 2, insert -- functional adenovirus -- between "the" and "100K".

In claim 218, line 3, delete the term "helper".

In claim 220, line 3, deleted the "particles".

In view of the above amendment, claims 2, 3, 16, 25, 132, and 147 have been canceled, and remaining claims 1, 4-5, 13, 15, 26-41, 59-70, 75, 80, 82-86, 94-98, 105-109, 111-116, 133, 146, 148 and 207-222 are allowable.

Petition to Correct Inventorship Under 37 C.F.R. 1.48(a)

In view of the petition to correct inventorship under 37 CFR § 1.48(a) filed on January 26, 2004, the verified Statement of inventor **Bradley L. Hodges** on 10/2/03, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding -- **Bradley L. Hodges** -- as co-inventors of this instant application.

The Bibliographic Data sheet has been changed to reflect the change of the inventorship. In addition, PTO PALM will be modified to reflect the updated inventorship.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0184**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **703-872-9306**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

DAVE T. NGUYEN
PRIMARY EXAMINER

Dave Nguyen
Primary Examiner
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